

DEPARTMENT OF HEALTH AND HUMAN SERVICES

JUN 28 1996

Mr. Edward W. Raleigh  
Manager  
Biotechnology Regulatory Affairs  
E. I. DuPont de Nemours & Company  
Walker's Mill  
Barley Mill Plaza  
Wilmington, Delaware 19898

Dear Mr. Raleigh:

This is in regard to DuPont's consultation with the Food and Drug Administration (FDA) (Center for Veterinary Medicine and Center for Food Safety and Applied Nutrition) on genetically modified cotton line 19-51a. According to DuPont, 19-51a cotton is modified to express a sulfonylurea herbicide tolerant form of the enzyme acetolactate synthase (ALS).

In September of 1995, DuPont initiated contact with FDA to discuss their proposed safety and nutritional assessment of cotton containing transformation event 19-51a. As part of bringing DuPont's consultation regarding this product to closure, DuPont submitted a summary assessment of cotton containing transformation event 19-51a on February 21, 1996.

These communications informed FDA of the steps taken by DuPont to ensure that this product complies with the legal and regulatory requirements that fall within FDA's jurisdiction. Based on the safety and nutritional assessment you have conducted, it is our understanding that DuPont has concluded that this new cotton variety is not materially different in composition, safety, or any other relevant parameter from cotton varieties currently on the market, and that it does not raise issues that would require premarket review or approval by FDA. All materials relevant to this notification have been placed in a file designated BNF0030. This file will be maintained in the Office of Premarket Approval.

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Based on the information DuPont has presented, we have no questions concerning this product at this time. However, as you are aware, it is DuPont's continued responsibility to ensure that food and feed derived from cotton line 19-51a are safe, wholesome, and in compliance with all applicable legal and regulatory requirements.

Sincerely yours,

/s/

Alan M. Rulis, Ph.D.  
Director  
Office of Premarket Approval  
Center for Food Safety  
and Applied Nutrition

cc: HFS-200 HFS-205 HFS-226 HFS-235 HFS-246 HFS-247  
HFS-13 HFS-144 HFV-200 HFV-221 HFV-226 BNF0030  
HFS-206